

# Special **REPORT**

## Quality of Life in Ventral and Hiatal Hernia Repair: *Review of Long-Term Patient Outcomes in Two Large Case Series*

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A fundamental goal of hernia repair is providing a durable closure.<sup>1</sup> Whether early or late, hernia recurrence is a complication associated with patient dissatisfaction<sup>2</sup> and increased costs.<sup>3</sup> Unlike many once-promising reinforcement materials abandoned as a result of failure or adverse outcomes,<sup>4</sup> the poly(glycolide:trimethylene carbonate) (PGA:TMC) copolymer bioabsorbable web scaffold GORE<sup>®</sup> BIO-A<sup>®</sup> Tissue Reinforcement remains a proven option for hernia repair after 10 years of widespread use.<sup>5,6</sup> Two distinct and extensive experiences with this bioabsorbable scaffold material—alone or incorporated into the hybrid hernia repair device GORE<sup>®</sup> SYNECOR Biomaterial<sup>7</sup>—demonstrate why appropriate tissue reinforcement with these unique biomaterials has been shown to lower the risk for hernia recurrence and may also preserve quality of life (QOL) for patients.

In one large series, as presented within this article, the surgeon reports revisions of ventral hernia repairs reinforced with the GORE<sup>®</sup> SYNECOR Intraoperative Biomaterial device remain exceedingly uncommon after follow-up out to 4 years. By combining the Gore proprietary, absorbable PGA:TMC copolymer materials with permanent knit to minimize the risk for both bacterial adherence and visceral attachment,<sup>7</sup> the integrity of the repair has remained largely unchanged when unrelated subsequent procedures provided an opportunity for second looks. In an ongoing case series in which the majority of the population is obese, often with additional risk factors for complications, this level of durability validates the underlying device design.

In a second large series, hiatal hernia repair was performed with GORE<sup>®</sup> BIO-A<sup>®</sup> Tissue Reinforcement alone in candidates for bariatric surgery. No patient had a body mass index (BMI) less than 35 kg/m<sup>2</sup>. Although tissue reinforcement continues to be used selectively in patients undergoing hiatal hernia repair,<sup>8</sup> the high risk for early recurrence in obese individuals<sup>9</sup> provided the rationale for routine use of a biodegradable reinforcement in this series. After 6 years, there were no complications related to tissue reinforcement device found, and no hernia repair has required revision.

In both series, these results, although impressive, do not tell the whole story. In the ventral hernia series, the absence of complications and symptoms, such as foreign body sensation, caused by the tissue reinforcement has helped restore patients to a pre-morbid QOL.

Similarly, durable hernia repair avoids the financial costs of additional second procedures.<sup>3</sup> In both situations, utilizing these innovative biomaterials for tissue reinforcement has been considered an investment by surgeons that is continuing to yield returns, as evaluated over multiple years of patient follow-up.

### Ventral Hernia Repair: Dr Mallico Case Series

According to recent guidelines, utilizing mesh to reinforce ventral hernias greater than 2 cm in width is recommended.<sup>10</sup> The surgical approach and type of tissue reinforcement in fulfilling this recommendation have been individualized according to an extensive list of considerations, such as relative hernia size and presence of comorbidities.<sup>10</sup> In clean surgical fields, the experience recounted by Dr Mallico and other clinicians is establishing the hybrid GORE® SYNECOR Biomaterial as a leading option. “A few studies have raised concern about laparoscopic bridging with tissue reinforcement especially in obese patients with comorbidities.<sup>11</sup> This has stemmed from the repair lacking strength and using materials with a higher risk for infection. It has led to a lot of clinicians searching for a new solution,” Dr Mallico said.

Many designs and concepts in tissue reinforcement have been created to address these issues. Despite voluntary withdrawals of many devices from the market, Dr Mallico estimated that more than 50 products remain in the United States. These are traditionally categorized into biologics; synthetic bioabsorbable, permanent meshes; and hybrid devices.<sup>12</sup> The effort to innovate within these categories has been driven by both early risk for failure, particularly among biodegradable devices, and late risk for complications, particularly among permanent devices.<sup>4</sup>

In abdominal wall repairs that require permanent repair to reduce the risk of late recurrence, GORE® SYNECOR Biomaterial is uniquely engineered to address characteristics often considered to be competing, such as strength and leaving minimal material behind.<sup>7</sup> The early clinical experience was consistent with the experimental development,<sup>13</sup> and now, 4 years after GORE® SYNECOR Biomaterial became commercially available,<sup>14</sup> case series, such as one by Dr Mallico, are tracking long-term experience.

In this series, data from which have been presented in part at several professional meetings, more than 225 abdominal wall repairs have been made with GORE® SYNECOR Biomaterial. The series began in 2016; more than 80% were performed laparoscopically. In repairs of ventral, incisional, incarcerated, or recurrent hernia, more than half were conventional intraperitoneal onlay mesh (IPOM) repairs. Nearly one-third involved an additional surgical procedure, such as inguinal hernia repair. The longest follow-up in this series is approaching 4 years, and the median follow-up is approximately 14 months (Figure 1). Over this time, there have been 3 recurrences, a rate substantially lower than expected in a population in which more than 60% of patients had a BMI greater than 30 kg/m<sup>2</sup>, nearly one-third had diabetes, and over 15% had a history of tobacco use. It also compares favorably to the recurrence rates that Dr Mallico had experienced with other tissue reinforcement devices. “I came to the GORE® SYNECOR Biomaterial for ventral repairs because I needed something better for the growing proportion of patients I see with risk factors that concerned me,” Dr Mallico said. “At this point, the majority of my IPOM cases are obese with or without additional risk factors, such as active tobacco use or diabetes.”

To date, there have been no reoperations within 90 days for infections or complications. Dr Mallico credits the low rate of recurrences to GORE® SYNECOR Biomaterial as well as to his specific strategies for improving the likelihood of a durable repair. “My technique has been to go big. With the tissue reinforcement, I plan for an overlap of at least 5 cm in all directions from the closure line,” he said. Although he had not anticipated a zero-recurrence rate in a large series with a high percentage of patients at elevated risk for complications, he noted that “I might not have gone wide enough with the 2 recurrences we did experience.”

Obesity, diabetes, and advancing age are known risk factors for ventral hernia recurrence,<sup>15</sup> but these and other risks are now common features in the general population, not just among those who require hernia repair. According to 2018 CDC data, the proportion of the US adult population with obesity, defined as a BMI greater than 30 kg/m<sup>2</sup>, reached 44.8% in those between 40 and 59 years of age.<sup>16</sup> “The challenge with obese patients is identifying a tissue replacement material that is strong, but poses a low risk of infection. Many surgeons have been reluctant to use permanent mesh devices in obese patients,” Dr Mallico said. “I think this hybrid mesh is proving to be the answer.”

Unlike conventional meshes, the hybrid design of GORE® SYNECOR Biomaterial involves combining absorbable and non-absorbable material to address competing issues. A macroporous knit of polytetrafluoroethylene (PTFE) monofilament fiber provides adequate strength, but is more resistant to bacterial adherence than other hernia devices.<sup>17</sup> A layer of PGA:TMC copolymer film is nonporous, lessening dense adhesion formation.<sup>7</sup> The Gore 3D PGA:TMC web scaffold is uniquely designed to encourage cell infiltration, tissue generation, and vascularity.<sup>5</sup> “With this hybrid approach, you receive the benefit of permanent reinforcement with the potential to have a low risk of infection, which is a major concern for surgeons repairing ventral hernias, particularly in the obese patient,” Dr Mallico said.

These relative attributes have been calibrated for specific risks. Pores are sufficiently large to allow sufficient tissue ingrowth, while reducing any scar plate formation without sacrificing strength required to sustain closure against abdominal



**Figure 1.** Robust collagen formation and vascularization observed at 13 months using GORE® SYNECOR Intraperitoneal Biomaterial.

Image courtesy of Eric J. Mallico, MD.

wall pressures.<sup>7</sup> This characteristic, expressed in ball burst strength, is measured objectively,<sup>7,18</sup> but long-term results with GORE® SYNECOR Biomaterial further demonstrate that the other major features, such as tissue ingrowth on the Gore 3D PGA:TMC scaffold and the low risk for adhesion formation on the PGA:TMC film,<sup>5,7</sup> are not theoretical.

“I have had the opportunity for second looks, and this is truly the reason that GORE® SYNECOR Biomaterial has become the only tissue reinforcement I use in ventral hernia repairs,” Dr Mallico said. “Even months after the procedure, I am not seeing significant adhesions. This saves a lot of time when you need to go back in for a cholecystectomy or another procedure unrelated to the prior hernia. Despite claims with other devices for a low risk of adhesions, this has not been my experience previously.”

GORE® SYNECOR Biomaterial also has practical attributes, according to Dr Mallico. “GORE® SYNECOR Biomaterial is available in a variety of sizes, but it also can be shaped during the procedure and customized to the patients’ needs without disrupting its strength or altering its integrity.<sup>7</sup> This is a phenomenal advantage,” he said. He also emphasized the advantages of the device’s composition, having a lightweight feel and very high strength, with a unique memory that allows the mesh to “pop right back into shape without kinks or distortions”—even after being manipulated through a trocar. In large hernias, Dr Mallico uses an open approach, but has developed a strategy in which he often performs a laparoscopic IPOM after the abdominal wall has been closed. “In obese patients with large hernias, the risk of recurrence is high.<sup>15</sup> So, I have been adding this extra layer of reinforcement to improve my outcomes. I have only had a single recurrence in over 20 cases using this approach,” he said.

Recurrences and reoperations can mean dissatisfied patients,<sup>2</sup> but Dr Mallico indicated that GORE® SYNECOR Biomaterial allows him to aim at an even higher goal. Now seeing patients several years out, he has found that GORE® SYNECOR Biomaterial allows patients to live life unaffected by their repaired hernia. According to Dr Mallico, without pain or foreign body sensation imposing restrictions, his patients return at their follow-up visits with a restored QOL.

## Hiatal Hernia Repair: Dr Scott Case Series

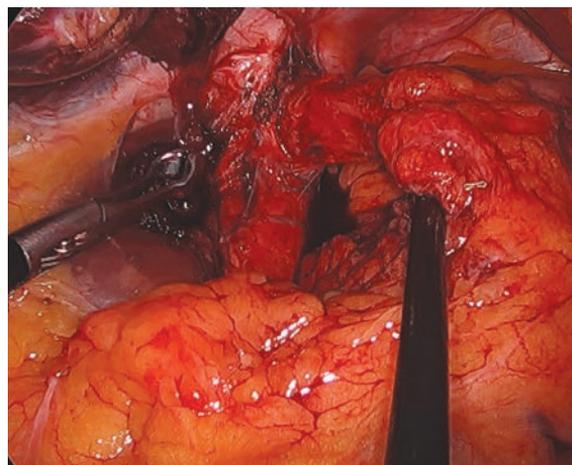
A case series evaluating outcomes with GORE® BIO-A® Tissue Reinforcement of hiatal hernias in candidates for bariatric surgery also can be regarded as sufficiently extensive to translate theory into practice. Tissue reinforcement is not a guideline standard for hiatal hernia repair, but the data from a large series of repairs starting in 2014 suggest that it could reasonably be adopted as a standard in patients with obesity.

With a median follow-up of more than 2.5 years, there has been zero operative recurrences or mesh-related complications, according to Dr Scott, who combined his own data with those of other bariatric surgeons with whom he practices (Figure 2). He has collected nearly 400 cases of hiatal hernia repairs with tissue reinforcement. Dr Scott does not repair all hiatal hernias prior to bariatric surgery, but he uses tissue reinforcement in all those he does repair. “It is important to avoid fixing something that does not need fixing. The function of the lower esophageal sphincter involves a complex relationship of muscles, so I do not necessarily repair a hiatal hernia if it is small and asymptomatic,” Dr Scott said.

Excessive body weight has long been recognized as an independent risk factor for hiatal hernia and associated complications, such as esophagitis,<sup>19</sup> but not all patients with hiatal hernia are obese, which may explain why the use of tissue reinforcement remains an area of debate despite evidence that this reduces the risk for hernia recurrence.<sup>20</sup> “The concern about permanent mesh is reasonable. If you place a hard or irritating material against the soft esophagus, the risk of complications is meaningful. This is an area moving with every breath. An erosion that involves the esophagus, for example, is a disaster,” Dr Scott said. Yet, the substantial pressure that a high volume of abdominal fat can place on a repaired hiatal hernia led Dr Scott to use GORE® BIO-A® Tissue Reinforcement, which adds repair strength during the healing process.<sup>5</sup> “GORE® BIO-A® Tissue Reinforcement is manufactured to specifications. Unlike biologics derived from animal tissue, its properties are uniform and predictable. I can be reassured that each device has a similar rate of degradation,” Dr Scott said. “To my knowledge, there has never been a case of erosion into the esophagus reported in the clinical literature with GORE® BIO-A® Tissue Reinforcement.”

Other clinicians have published data in support of tissue reinforcement in hiatal hernia repairs, particularly in obese patients,<sup>21</sup> but this long follow-up, which has included some second looks, “gives me confidence that GORE® BIO-A® Tissue Reinforcement is doing what it is supposed to be doing.” Citing an earlier hiatal hernia study, in which the lower recurrence rate with tissue reinforcement (9% vs 24%) was offered as proof of the benefit,<sup>22</sup> Dr Scott suggested that the zero reoperation rate with GORE® BIO-A® Tissue Reinforcement in this case series speaks for itself.

“Is reinforcement necessary for the repair of hiatal hernias in patients who are candidates for bariatric surgery? Based on the data in our patient population, it is invaluable,” Dr Scott said. “For those concerned about the increased per-case cost by adding tissue reinforcement, it is only necessary to look at the costs of a complication. This is an investment in an optimal outcome.”



**Figure 2.** Seven-year second look at GORE® BIO-A® Tissue Reinforcement used in hiatal hernia repair.

Image courtesy of John D. Scott, MD.

In an obese population, hiatal hernias can be expected in close to 40% of patients.<sup>23</sup> Although looking for these anomalies is not the only reason that Dr Scott performs a preoperative endoscopy in essentially every patient who is candidate for bariatric surgery, he said repair is critical to an optimal long-term result. In surgery of obese patients, with many potential risks for adverse outcomes, tissue reinforcement has been reducing the risk for hernia recurrence.<sup>21</sup> "In my population, even late complications are a bad result. I do not want to see a recurrent hernia at 3 years or at 7 years. I will see most of these patients for the rest of their lives," he said.

Ultimately, the goal of bariatric surgery is weight loss, but successful hernia repair in this patient population means protection from many of the complications that adversely affect QOL, such as the esophagitis complicated by hiatal hernias.<sup>19</sup> Optimal levels of patient satisfaction depend on optimal long-term results.

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## Conclusion

The history of tissue reinforcement has been replete with novel materials and devices,<sup>13</sup> but advantages remain theoretical until the absence of long- and short-term complications can be confirmed. The experience with GORE® SYNECOR Biomaterial, which unites the proven technologies of PTFE monofilament fibers and the biosynthetic Gore3D PGA:TMC web scaffold,<sup>7</sup> in high-risk obese patients is now within a time frame that supports more insights related to long-term results. GORE® BIO-A® Tissue Reinforcement has been in clinical use for over 12 years, demonstrating reliable reinforcement during the critical wound healing period.<sup>5,6</sup> Long-term clinical experiences with both materials reinforce the opportunity they can provide for repairs that increase the likelihood of favorable long-term outcomes and preservation of patient QOL.